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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,001	05/01/2002	Mark A Samuels	19141.0035U3	7089
23859	7590	03/15/2004		
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER KREMER, MATTHEW J	
			ART UNIT 3736	PAPER NUMBER 11

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,001

Applicant(s)

SAMUELS ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,10-13,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,14-19,23,24,29,30,32,33,41 and 42 is/are rejected.
- 7) ☒ Claim(s) 20, 25-28, 31, 34-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on a PCT application filed on June 12, 2000. It is noted, however, that applicant has not filed a certified copy of the PCT/US00/16064 application as required by 35 U.S.C. 119(b). It is further noted that the present application is a 371 of the PCT application and a claim of foreign priority to PCT/US00/16064 is not necessary and is improper.

Claim Objections

2. Claim 18 is objected to because of the following informalities. In claim 18, line 2, "detect" should be "detects".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "the energy absorbing apparatus" in line 3 in which there is insufficient antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8-9, 14, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,274,418 to Vesterager et al. (cited by Applicant). Vesterager et al. discloses an alignment device comprising a tissue interface member 12 for position on the surface of the tissue 20 and mating with one apparatus 10. (Fig. 4 of Vesterager et al.). In regard to claims 8-9, the alignment device has an exterior surface (the location where reference numeral 12 is pointing) and an interior surface (the location where threads 9 are screwed into the alignment device). (Fig. 4 of Vesterager et al.). In regard to claim 14, an adhesive element 17 is discloses. (Figs. 2 and 4 of Vesterager et al.). In regard to claim 41, sensor device 10 includes a housing that has one opening in the form of a semi-permeable membrane 8 (which is considered to have many openings) and at least on alignment member in the form of threads 16. (Fig. 6 of Vesterager et al.). It is noted that the limitation “to collect biological fluid from tissue” was used to describe “at least one opening in the housing” but this is merely “intended use” language, which cannot be relied upon to define over Vesterager et al., since Vesterager discloses all of

the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647.

6. Claims 1, 8-9, 14, 17, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,879,373 to Roper et al. (cited by Applicant). Roper et al. teaches an alignment device 20 and an apparatus 10. (Fig. 1A of Roper et al.). In regard to claims 8-9, the alignment device has an exterior surface (the location where reference numeral 20 is pointing) and an interior surface (the location where reference numeral 28 is pointing). (Fig. 1A of Roper et al.). In regard to claim 14, an adhesive layer 22 is disclosed. (Fig. 1A of Roper et al.). In regard to claim 17, a light emitter 13 is disclosed. (Fig. 1A of Roper et al.). In regard to claim 42, Roper et al. discloses an energy source 13 and at least one alignment member 26. (Fig. 1A of Roper et al.). In regard to claim 42, the limitation "suitable for absorption by an energy absorbing layer position in substantial contact with a surface of a tissue" was not given patentable weight since it is not part of the claimed "energy emitter apparatus." Regardless, Roper et al. teaches an energy emitter that produces energy, which is suitable for absorption by different layers including skin.

7. Claims 1, 8-9, 14-15, 17, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,381,489 to Ashibe. Ashibe teaches an alignment device 2 and an apparatus 3/4. (Fig. 1A of Ashibe). In regard to claims 8-9, the alignment device has an exterior surface (the location where reference numeral 2 is pointing) and an

interior surface (the location where reference numerals 3 and 5 will be inserted). (Fig. 1A of Ashibe et al.). In regard to claims 14-15, an adhesive or strap can be used. (column 5, lines 1-12 of Ashibe). In regard to claim 17, a light emitter 3 is disclosed. In regard to claim 42, Ashibe discloses an energy source 3 and at least one alignment member (the outside diameter 12). (Figs. 8-10 of Ashibe). In regard to claim 42, the limitation "suitable for absorption by an energy absorbing layer position in substantial contact with a surface of a tissue" was not given patentable weight since it is not part of the claimed "energy emitter apparatus." Regardless, Ashibe teaches an energy emitter that produces energy, which is suitable for absorption by different layers including skin.

8. Claims 1, 8-9, 17-19, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,556,372 to Talish et al. (cited by Applicant). Talish et al. discloses an alignment device comprising a tissue interface member 102 (Fig. 11 of Talish et al.) for position on the surface of the tissue and mating with one apparatus 14. (Fig. 13 of Talish et al.). In regard to claims 8-9, the alignment device has an exterior surface and an interior surface (the location where threads 104 are screwed into the alignment device). (Fig. 13 of Talish et al.). In regard to claims 17-19, Talish et al. teaches the lugs 116 act as a sensor, which triggers the ultrasonic treatment when apparatus 14 is properly positioned. (column 7, lines 35-47 of Talish et al.). In regard to claim 18, by using the broadest reasonable interpretation, the lugs 116 are considered to be the sensors since they detect when the ultrasonic emitter is in position and then activate the controller by closing the circuit. In regard to claim 19, the lugs 116 are

considered the pressure sensors since the lugs are responsive to sufficient pressure from engagement with the interface member 102. In regard to claim 42, Talish et al. discloses an energy source 14 and at least one alignment member (the outside diameter 118). (Fig. 13 of Talish et al.). In regard to claim 42, the limitation "suitable for absorption by an energy absorbing layer position in substantial contact with a surface of a tissue" was not given patentable weight since it is not part of the claimed "energy emitter apparatus." Regardless, Talish et al. teaches an energy emitter that produces energy, which is suitable for absorption by different layers including skin.

9. Claims 1, 8-9, 14, 16, 23-24, 29-30, 32-33, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,568,806 to Cheney, II et al. In regard 1, Cheney, II et al. teaches a tissue interface member 30 and an apparatus 16. (Fig. 2 of Cheney, II et al.). In regard to claim 14, adhesive is used. (column 4, lines 7-14 of Cheney, II et al.). In regard to claims 16 and 29-30, fluid is collected in the cannula 15. (column 5, lines 14-23 of Cheney, II et al.). In regard to claims 23-24, Cheney, II et al. teaches a tissue interface member 30, a tissue-breaching device 14 by mechanical means, and a sensor device 16. (Fig. 2 of Cheney, II et al.). In regard to claim 32, the method of Cheney, II et al. discloses placing the interface member 30 on the skin, mating the tissue-breaching device 14 with the interface member 30 while at the same time mating the sensor device 16 with the interface member 30, activating the tissue-breaching device 14 by pushing device 14 into the skin while at the same time inserting the sensor device 16, and removing the tissue-breaching device 14. In regard

to claim 41, Cheney, II et al. teaches a housing 15, at least one opening 19, and at least one alignment member (the outer diameter of the housing) for mating with a complementary alignment member 30. (Fig. 3 of Cheney, II et al.).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,885,211 to Eppstein et al. (cited by Applicant) in view of U.S. Patent 5,671,317 to Weishaupt et al. Eppstein et al. teaches the use of tissue ablation for microporation of the skin. (column 15, line 6 to column 16, line 60 of Eppstein et al.). Eppstein et al. teaches the use of an optical delivery system 72. (Fig. 2 of Eppstein et al.). Eppstein et al. does not teach the use of an alignment device. Weishaupt et al. teaches the use of an alignment device (Abstract and Fig. 2 of Weishaupt et al.), which is used to stabilize the optical delivery system to the skin. (column 1, lines 41-55 of Weishaupt et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the alignment device of Weishaupt et al. in the invention of Eppstein et al. since the alignment device will stabilize the optical delivery system relative to the skin. In regard to claim 1, the combination teaches the use of an

alignment device (Fig. 2 of Weishaupt et al.) that would engage the optical delivery system (reference number 72 of Eppstein et al.). In regard to claim 5, the limitation that the tissue interface member mates with a first and second apparatus is satisfied since the apparatus of Weishaupt et al. is used for the mating of several types of apparatus. It should be noted that the Examiner interpreted claim 5 such that no patentable weight was given to the limitations relating to the first and second apparatuses since claim 5 is merely drawn to the alignment device and not a system comprising the alignment device, a first apparatus, and a second apparatus.

Allowable Subject Matter

12. Claims 20, 25-28, 31, and 34-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is an examiner's statement of reasons for allowance. In regard to claim 20, the prior art does not teach or suggest a controller of the energy emitter that is responsive to both the switch and the pressure sensor. In regard to claim 25, the prior art does not teach or suggest an energy absorbing layer attached to the tissue interface member. In regard to claim 31, the prior art does not teach or suggest drawing biological fluid using a suction force. In regard to claim 34, the prior art does not teach or suggest mating an energy emitter device to the tissue interface member, activating

the energy emitter for ablation, detaching the energy emitter device, and removing the energy absorbing layer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

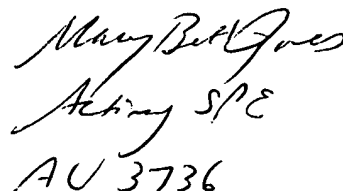
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew Kremer



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